

providing a disposable article adapted to be worn by the wearer;

associating one or more compositions for enhancing the removability of fecal waste from the skin of the wearer with said disposable article so that said one or more compositions are available to at least a portion of one of said bodily waste and said skin of said wearer;

said one or more compositions providing one or more of the following as determined by the test methods set forth in the specification:

- a) a mean Waste Contamination Area of less than about 15 cm<sup>2</sup>;
- b) a mean Waste Contamination Mass calculated from the equation  $\sum_{L0}^{Ln}$   
 $(mArArea \times mArGV)/255$  of less than about 14 mass units.

### REMARKS

#### Objection to IDS:

The Examiner noted in the Office Action that the Information Disclosure Statement filed on 10/25/99 did not include copies of the references to be considered. Thus, the Examiner stated that the IDS was placed in the file wrapper and would not be considered. Applicants' attorney respectfully requests that the Examiner's decision with respect to the IDS be reconsidered. As stated in the IDS, page 2, copies of the references were not provided in accordance with 37 CFR 1.98(d) which states in part:

[a] copy of any patent . . . listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 USC 120.

All of the documents listed on the IDS in question were cited by or submitted to the Office in Application Serial Nos. 09/107,561 filed 6/29/98; 09/106,255 filed 6/29/98 and 08/970,508 filed 11/14/97, which are relied upon for an earlier filing date under 35 USC 120. Accordingly, Applicants' attorney respectfully requests that the

references cited in the IDS filed on 10/22/99 be considered. (For the Examiner's convenience, and as agreed to during a telephone conversation with the Examiner, copies of the foreign references cited in the IDS are being submitted herewith.)

Objection to Specification:

The Examiner objected to certain portions of the specification (Table VIII and pages 76-77) because there are no units associated with the heading "Waste Contamination Mass". Applicants' attorney traverses the objection and respectfully requests its reconsideration and withdrawal.

As noted in the table on page 55 of the specification, the units associated with the Waste Contamination Mass measurement are "mass units". The particular method of measuring Waste Contamination Mass in mass units is described in detail in the Calculations portion of the specification, at pages 76-77. Further, the specification has been amended to make it clear on page 54 that "mass units" are the units that correspond to the measurement of Waste Contamination Mass. Thus, it should be clear to one of ordinary skill in the art to look to the Calculations portion of the specification to get better understanding of Waste Contamination Mass and how it is calculated if it is not already clear from the rest of the specification. Accordingly, Applicants' attorney requests that the objection to the specification be withdrawn.

With respect to the chart on page 77, Applicants' attorney again points the Examiner to the explanation of Waste Contamination Mass and its calculation throughout the specification and especially on pages 54-55 and 76-77. However, to make the chart even more clear, the units "cm<sup>2</sup>" and "mass units" have been added to the chart at the appropriate locations. No new matter is added by the proposed amendments to the specification.

Accordingly, Applicants' attorney requests that the objection to the specification be withdrawn.

Rejection under 35 USC 112:

The Examiner rejected all of the claims under 35 USC 112, first paragraph, as based on a disclosure which is non-enabling. As with the objection to the

specification, the Examiner focused on the units associated with the Waste Contamination Mass. Despite the fact that “mass units” are specifically called out in the claims to be the units associated with Waste Contamination Mass, the Examiner states that units are not set forth in the claims and thus, one of ordinary skill in the art would not be able to determine the scope of the claims.

Applicants’ attorney respectfully traverses the rejection and requests its reconsideration and withdrawal.

As noted above, the specification gives a detailed description of what the measurement Waste Contamination Mass refers to and how it is measured. (See, for example pages 54-55 and 76-77.) Further, the specification explicitly sets forth that the value of the Waste Contamination Mass is expressed in “mass units” (see page 76, line 24). Applicants express the Waste Contamination Mass in “mass units” to simplify the specification and the claims, and to emphasize that the measurement relates to the relative fecal mass remaining on the skin after the skin is wiped according to the test procedures in the specification. Specifically, the Waste Contamination Mass is a measurement of the fluorescing fecal analog remaining on the skin after the skin is wiped in accordance with the methods set forth in the Methods section of the specification. (pages 67-77) The mean Waste Contamination Mass is calculated by summing all of the calculated values corresponding to the equation  $\sum_{L0}^{Ln} (mArArea \times mArGV)/255$  for the particular skin specimen analyzed and then calculating the arithmetic mean of all of the sums obtained from the skin specimens analyzed that are of the same composition. (See page 76, lines 23-27.) The measurement “mArArea” corresponds to the area in square calibrated units (e.g.  $cm^2$ ) of an area object, and the measurement “mArGV” corresponds to the mean scaled luminance (in gray scale units) of pixels within an area boundary. When multiplied together and divided by 255 (the maximum gray scale value), the resulting value is the Waste Contamination Mass, which could be expressed in area times fraction of maximum potential brightness, (i.e.  $cm^2$  times gray scale units divided by maximum gray scale value), or more easily in Applicants’ clearly defined “mass units”.

For the above reasons, Applicants’ attorney believes that the specification and claims as originally drafted are clear and enabling to one of ordinary skill in the art. However, Claims 28, 31-33 and 58 have been amended to include the equation from

which the mean Waste Contamination Mass is derived. The Examiner requested that this amendment be made during a telephone conversation with Applicants' attorney on January 31, 2001. With the equation in the relevant claims, the Examiner has stated that the question of indefiniteness would be overcome. (See Paper No. 11 mailed 2/6/01.) Accordingly, Applicants' attorney requests that the rejection be withdrawn and that Claims 28-37, 40-44, 47-49 and 58-60 be allowed.

### CONCLUSION

Applicants have elected to prosecute claims 28-37, 40-44, 47-49 and 58-60.


All of the Examiner's rejections and objections have been addressed. The proposed amendments to the specification and claims do not add new matter and are made merely to help the Examiner understand what would be readily apparent to one of ordinary skill in the art.

Accordingly, Applicants attorney respectfully requests that the pending claims be allowed.

Respectfully submitted,

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